**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| DUCHESNAY INC., SHIONOGI INC., and QUATRX PHARMACEUTICALS COMPANY,<br><br>*Plaintiffs,*<br><br>v.<br><br>HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, and HETERO USA, INC.,<br><br>*Defendants.* | C.A. No. 21-538-LPS |

**DEFENDANTS HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, AND HETERO USA, INC.'S ANSWER TO PLAINTIFFS' COMPLAINT**

Defendants Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero"), by its undersigned attorneys, hereby answer the Complaint (D.I. 1) ("Complaint") concerning U.S. Patent No. 8,642,079 ("the '079 patent").

**GENERAL DENIAL**

Hetero denies all allegations in Plaintiffs' Complaint except for those specifically admitted below. With respect to the allegations made in the Complaint, upon knowledge with respect to Hetero's own acts, and upon information and belief as to other matters, Hetero responds and alleges as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement of United States Patent No. 8,642,079 ("the '079 patent") arising under the United States Patent Laws, Title 35, United States Code, § 1, et. seq., and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 215574, which Hetero filed or caused to be filed under 21 U.S.C. § 355(j) with the U.S. Food and Drug Administration (the "FDA") for

approval to market in the United States a generic copy of Plaintiffs' Osphena® product prior to the expiration of the '079 patent.

**ANSWER:** Hetero admits that the above-captioned action purports to be an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, in response to Hetero's submission of ANDA No. 215574 ("Hetero's ANDA Product") to the United States Food and Drug Administration ("FDA").

**THE PARTIES**

2. Duchesnay is a Canadian corporation with its headquarters at 950 Boulevard Michele-Bohec, Blainville, Quebec, Canada J7C 5E2.

**ANSWER:** Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2, and therefore denies them.

3. Duchesnay is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for women's health.

**ANSWER:** Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3, and therefore denies them.

4. Shionogi is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

**ANSWER:** Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4, and therefore denies them.

5. Shionogi is engaged in the business of researching, developing, and bringing to market innovative pharmaceutical products.

**ANSWER:** Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5, and therefore denies them.

6. QuatRx is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

**ANSWER:** Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6, and therefore denies them.

7. On information and belief, Hetero Labs is a corporation organized and existing under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500018, Telangana, India.

**ANSWER:** Admitted.

8. On information and belief, Hetero Unit-V is a division of Hetero Labs, with its principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

**ANSWER:** Admitted.

9. On information and belief, Hetero Drugs is a corporation organized under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500018, Telangana, India.

**ANSWER:** Admitted.

10. On information and belief, Hetero USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

**ANSWER:** Admitted.

11. On information and belief, Hetero USA is the U.S. Regulatory Agent for Hetero Labs, Hetero Unit-V, and Hetero Drugs.

**ANSWER:** Hetero admits that Hetero USA is the U.S. regulatory agent for ANDA No. 215574 and Hetero's ANDA Product. Hetero denies the remaining allegations contained in Paragraph 11.

12. On information and belief, Hetero Drugs and Hetero Labs each own a 50% share of Hetero USA.

**ANSWER:** Admitted.

## JURISDICTION AND VENUE

13. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

**ANSWER:** Hetero incorporates its Answers to the foregoing paragraphs of the Complaint as if fully set forth herein.

14. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, et seq., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**ANSWER:** Paragraph 14 contains conclusions of law to which no response is required. To the extent that a response is required, Hetero admits that this action arises under the patent laws of the United States of America. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 14.

15. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Paragraph 15 contains conclusions of law to which no response is required. To the extent that a response is required, Hetero admits that this Court has subject matter jurisdiction to adjudicate this action. Hetero denies any remaining allegations or legal conclusions contained in Paragraph 15.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero USA is incorporated in the State of Delaware.

**ANSWER:** Paragraph 16 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest venue in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 16.

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Labs and Hetero Drugs are incorporated in India and may be sued in any judicial district in the United States.

**ANSWER:** Paragraph 17 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not

contest venue in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 17.

18. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Unit-V is a division of Hetero Labs, which is incorporated in India and may be sued in any judicial district in the United States.

**ANSWER:** Paragraph 18 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest venue in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 18.

19. On information and belief, venue is also proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero is an ANDA submitter and its connections to this forum are sufficiently related to the ANDA submission.

**ANSWER:** Paragraph 19 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest venue in this Court for purposes of this action only. Hetero further admits that Hetero Labs Ltd. Unit-V, Hetero Labs Ltd., and Hetero USA, Inc. submitted ANDA No. 215574. Hetero denies any remaining allegations or legal conclusions in Paragraph 19.

20. This Court has personal jurisdiction over Hetero Labs. On information and belief, Hetero Labs is in the business of, *inter alia*, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero Labs directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Labs purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

**ANSWER:** Paragraph 20 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 20.

21. On information and belief, Hetero Labs "is a research based global pharmaceutical company focused on development, manufacturing and marketing of Active Pharmaceutical Ingredients (APIs), Intermediate Chemicals & Finished Dosages." https://www.indiamart.com/heterolabs-limited/aboutus.html (Hetero Labs Ltd. Profile, accessed Apr. 9, 2021).

**ANSWER:** The website https://www.indiamart.com/heterolabs-limited/aboutus.html speaks for itself. Hetero denies the remaining allegations of Paragraph 21.

22. This Court has personal jurisdiction over Hetero Unit-V. On information and belief, Hetero Unit-V is in the business of, inter alia, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero Unit-V directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Unit-V purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

**ANSWER:** Paragraph 22 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 22.

23. On information and belief, Hetero Unit-V is the drug manufacturing facility for Hetero Labs and manufactures Hetero's generic products. *See, e.g.*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hetero-labs-limited-unit-v-520359-08152017 (letter from the FDA to recipient Hetero Unit-V, accessed Apr. 9, 2021).

**ANSWER:** The website https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hetero-labs-limited-unit-v-520359-08152017 speaks for itself. Hetero denies the remaining allegations of Paragraph 23.

24. This Court has personal jurisdiction over Hetero Drugs. On information and belief, Hetero Drugs is in the business of manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero Drugs, directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Drugs purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

**ANSWER:** Paragraph 24 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 24.

25. On information and belief, Hetero Drugs admits it "is one of India's leading generic pharmaceutical companies" and it "has a strong global presence in over 126 countries[.]" https://www.heteroworld.com/company-profile.php (accessed Apr. 9, 2021). On information and belief, Hetero Drugs admits that "our R&D has been able to develop niche generics" and that "ANDAs and FTFs accredited to us showcase our strength in R&D." https://www.heteroworld.com/research.php (accessed Apr. 9, 2020).

**ANSWER:** The websites https://www.heteroworld.com/company-profile.php and https://www.heteroworld.com/research.php speak for themselves. Hetero denies the remaining allegations of Paragraph 25.

26. This Court has personal jurisdiction over Hetero USA. On information and belief, Hetero USA is organized and existing under the laws of the State of Delaware. On information and belief, Hetero USA is in the business of, *inter alia*, manufacturing, marketing, importing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Hetero USA directly, or indirectly, develops, manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

**ANSWER:** Paragraph 26 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 26.

27. On information and belief, Hetero USA, Inc. admits it is "the US representation of HETERO, a privately owned; research based global pharmaceutical company" and that "[w]e have a significant presence in the development and marketing of finished dosages." See https://h1bdata.com/pin/hetero-usa/ (accessed Apr. 9, 2021).

**ANSWER:** The website https://h1bdata.com/pin/hetero-usa/ speaks for itself. Hetero denies the remaining allegations of Paragraph 27.

28. On information and belief, Hetero USA maintains continuous and systematic contacts with Delaware through its authorized Delaware registered agent, W/K Incorporating Services, Inc., located at 3500 South DuPont Highway, Dover, DE 19901.

**ANSWER:** Paragraph 28 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 28.

29. On information and belief, the acts of Hetero complained of herein were done with the cooperation, participation, and assistance of Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA.

**ANSWER:** Paragraph 29 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 29.

30. On information and belief, and consistent with Hetero's practice with respect to other generic products, following FDA approval of ANDA No. 215574, Hetero will act in concert to distribute and sell the generic product described in ANDA No. 215574 ("Hetero's Generic Product") throughout the United States, including the State of Delaware.

**ANSWER:** Paragraph 30 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 30.

31. This Court has personal jurisdiction over Hetero Labs, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Labs is organized under the laws of India.

**ANSWER:** Paragraph 31 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 31.

32. This Court has personal jurisdiction over Hetero Unit-V, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Unit-V is organized under the laws of India.

**ANSWER:** Paragraph 32 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 32.

33. This Court has personal jurisdiction over Hetero Drugs, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Labs is organized under the laws of India.

**ANSWER:** Paragraph 33 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 33.

34. This Court has personal jurisdiction over Hetero USA because, *inter alia*, Hetero USA is organized and existing under the laws of the State of Delaware.

**ANSWER:** Paragraph 34 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 34.

35. This Court also has personal jurisdiction over Hetero because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Hetero satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State"), and § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State").

**ANSWER:** Paragraph 35 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not

contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 35.

36. On information and belief, the effort to seek approval for ANDA No. 215574 and to manufacture, import, market, and/or sell Hetero's Generic Product upon approval has been a cooperative and joint enterprise and venture between Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA.

**ANSWER:** Paragraph 36 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 36.

37. On information and belief, Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 215574 and in commercializing Hetero's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 215574 upon approval.

**ANSWER:** Paragraph 37 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 37.

38. On information and belief, Hetero Labs, Hetero Labs Unit-V, Hetero Drugs, and Hetero USA hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

**ANSWER:** Paragraph 38 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 38.

39. On information and belief, Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 215574.

**ANSWER:** Paragraph 39 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 39.

40. This Court has personal jurisdiction over Hetero by virtue of the fact that it has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs.

**ANSWER:** Paragraph 40 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 40.

41. This Court also has personal jurisdiction over Hetero because Hetero has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Hetero, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Hetero's website states that its "[b]randed generics division is intended to bring access to high-quality medicines within affordable reach of markets across the globe" and identifies the United States as part of its global footprint. *See* https://www.heteroworld.com/branded-generics.php, https://www.heteroworld.com/global-footprint.php (accessed Apr. 9, 2021). On information and belief, Hetero derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

**ANSWER:** Paragraph 41 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, the websites https://www.heteroworld.com/branded-generics.php and https://www.heteroworld.com/global-footprint.php speak for themselves. Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 41.

42. This Court also has personal jurisdiction over Hetero because it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Hetero has

previously invoked this Court's jurisdiction by asserting counterclaims in at least seven cases in the last four years. *See, e.g., Gilead Sciences, Inc. v. Apotex, Inc.*, No. 20-189 (D. Del. Apr. 13, 2020), *Novartis Pharm. v. Dr. Reddy's Labs., Inc.*, No. 19-2053 (D. Del. Jan. 27, 2020), *Genentech, Inc. v. Hetero Labs Ltd*, No. 19-178 (D. Del. Apr. 1, 2019), *Biogen Int'l GMBH v. Amneal Pharm. LLC*, No. 17-823 (D. Del. Mar. 21, 2019), *Novartis Pharm. v. Accord Healthcare Inc.*, No. 18-1043 (D. Del. Aug. 9, 2018), *Biogen Int'l GMBH v. Hetero USA Inc.*, No. 17-825 (D. Del. Oct. 16, 2017), *Bristol-Myers Squibb Co. v. Hetero USA Inc.*, No. 17-376 (D. Del. Jun. 16, 2017).

**ANSWER:** Paragraph 42 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 42.

43. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Hetero.

**ANSWER:** Paragraph 43 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero does not contest personal jurisdiction over it in this Court for purposes of this action only. Hetero denies any remaining allegations or legal conclusions in Paragraph 43.

## FACTUAL BACKGROUND

### The NDA

44. Duchesnay is the holder of New Drug Application ("NDA") No. 203505 for Osphena® (ospemifene) tablets.

**ANSWER:** Paragraph 44 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero admits that the electronic version of FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") lists "Duchesnay Inc." as the apparent holder of NDA No. 203505 for OSPHENA® (ospemifene) tablets, 60 mg dosage strength. Hetero further admits that the Orange Book lists the active ingredient in OSPHENA® as "ospemifene." Hetero

lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations of Paragraph 44, and therefore denies them.

45. The FDA approved NDA No. 203505 on February 26, 2013, for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause, and on January 25, 2019, for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.

**ANSWER:** Paragraph 45 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero admits that on its face the current publicly available label associated with NDA No. 203505, which was last updated January 2019, states that OSPHENA® is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause; and the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause. Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations of Paragraph 45, and therefore denies them.

**The Patent-in-Suit**

46. The ’079 patent, titled “Solid Formulations of Ospemifene,” was duly and legally issued by the United States Patent and Trademark Office on February 4, 2014. A true and correct copy of the ’079 patent is attached as Exhibit A.

**ANSWER:** Paragraph 46 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero admits that on its face, the ’079 patent states that it issued on February 4, 2014. Hetero also admits that on its face, the ’079 patent is titled “Solid Formulations of Ospemifene.” Hetero admits that what purports to be a copy of the ’079 patent was attached to the Complaint as Exhibit A. Hetero denies that the ’079 patent was duly and legally issued. Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 46, and therefore denies them.

47. QuatRx owns the rights to the '079 patent. Duchesnay and Shionogi are exclusive licensees in the United States of the '079 patent. The '079 patent expires on July 9, 2028.

**ANSWER:** Hetero admits that the electronic version of the Orange Book currently lists the '079 patent expiration date as July 9, 2028. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 47, and therefore denies them.

48. The '079 patent is listed in the FDA Orange Book in connection with NDA No. 203505 for Osphena® (ospemifene) tablets.

**ANSWER:** Paragraph 48 of the Complaint contains allegations and/or conclusions of law to which no response is required. To the extent a response is required, Hetero admits that the electronic version of the Orange Book currently lists, *inter alia*, the '079 patent in connection with OSPHENA®. Hetero denies any remaining allegations or legal conclusions in Paragraph 48.

**The ANDA**

49. On information and belief, Hetero filed ANDA No. 215574 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of ospemifene tablets, which is a generic version of Plaintiffs' Osphena® (ospemifene) tablets.

**ANSWER:** Hetero admits that Hetero Labs Ltd. Unit-V, Hetero Labs Ltd., and Hetero USA, Inc. filed ANDA No. 215574 with the FDA to obtain FDA approval for the commercial manufacture and sale in the United States of ospemifene tablets, 60 mg. Hetero denies the remaining allegations in Paragraph 49.

50. On information and belief, ANDA No. 215574 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications"), alleging that the claims of the '079 patent are invalid, unenforceable, and/or would not be infringed by Hetero's Generic Product.

**ANSWER:** Admitted.

51. On March 1, 2021, Duchesnay received a letter sent by Hetero, dated February 26, 2021, purporting to be a "Notice of Certification" for ANDA No. 215574 ("Hetero's Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §

314.95. Hetero's Notice Letter notified Duchesnay that Hetero had filed ANDA No. 215574, seeking approval to market Hetero's Generic Product prior to the expiration of the '079 patent.

**ANSWER:** Hetero admits that it sent written notice of its ANDA and its Paragraph IV certification to Duchesnay. Hetero further admits that it certified that the claims of the '079 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation into the United States the product described in ANDA No. 215574. Hetero denies the remaining allegations in Paragraph 51.

52. Plaintiffs commenced this action within 45 days of receiving Hetero's Notice Letter.

**ANSWER:** Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 52, and therefore denies them.

**COUNT I**
**Infringement of the '079 Patent**

53. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

**ANSWER:** Hetero incorporates its Answers to the foregoing paragraphs of the Complaint as if fully set forth herein.

54. On information and belief, Hetero filed ANDA No. 215574 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the '079 patent.

**ANSWER:** Hetero admits that it filed ANDA No. 215574 seeking to obtain marketing approval for its generic 60 mg ospemifene tablets. Hetero denies the remaining allegations contained in Paragraph 54.

55. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.95(c)(2), a certification that the claims of the '079 patent are purportedly invalid, unenforceable, and/or not infringed.

**ANSWER:** Admitted.

56. On information and belief, in its ANDA No. 215574, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' Osphena® (ospemifene) tablets.

**ANSWER:** Hetero admits that in ANDA No. 215574, Hetero Labs Ltd. Unit-V, Hetero Labs Ltd., and Hetero USA, Inc. states that "results are showing that the proposed drug product, Ospemifene Tablets 60 mg of Hetero labs Limited is bioequivalent to Reference Listed Drug, OSPHENA ® 60 mg of Duchesnay Inc." Hetero denies the remaining allegations of Paragraph 56.

57. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 215574 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '079 patent, constitutes infringement, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

58. In Hetero's Notice Letter, Hetero did not allege noninfringement of claims 1-18 of the '079 patent, and therefore admits infringement of those claims.

**ANSWER:** Denied.

59. Upon FDA approval of ANDA No. 215574, Hetero will infringe one or more claims of the '079 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215574 shall be no earlier than the expiration of the '079 patent and any additional periods of exclusivity.

**ANSWER:** Denied.

60. On information and belief, Hetero has knowledge of the '079 patent and has filed ANDA No. 215574 seeking authorization to commercially manufacture, use, offer for sale, and sell Hetero's Generic Product in the United States. On information and belief, if the FDA approves ANDA No. 215574, physicians, health care providers, and/or patients will use Hetero's Generic Product according to Hetero's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '079 patent in violation of Plaintiffs' patent rights.

**ANSWER:** Hetero admits that it has knowledge of the '079 patent. Hetero further admits that Hetero Labs Ltd. Unit-V, Hetero Labs Ltd., and Hetero USA, Inc. filed ANDA No.

215574 with the FDA to obtain FDA approval for the commercial manufacture and sale in the United States of ospemifene tablets, 60 mg. Hetero denies the remaining allegations in Paragraph 60.

61. On information and belief, Hetero knows and intends that physicians, health care providers, and/or patients will use Hetero's Generic Product according to Hetero's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '079 patent with the requisite intent under 35 U.S.C. § 271(b).

**ANSWER:** Denied.

62. On information and belief, if the FDA approves ANDA No. 215574, Hetero will sell or offer to sell Hetero's Generic Product specifically labeled for use in practicing one or more claims of the '079 patent, wherein Hetero's Generic Product is a material part of the invention claimed in the '079 patent, wherein Hetero knows that physicians will prescribe and patients will use Hetero's Generic Product for practicing one or more claims in the '079 patent, and wherein Hetero's Generic Product are especially adapted for a use that infringes the '079 patent and are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants will thus contribute to the infringement of the '079 patent under 35 U.S.C. § 271(c).

**ANSWER:** Denied.

63. On information and belief, Hetero's actions relating to Hetero's ANDA No. 215574 complained of herein were done by and for the benefit of Hetero.

**ANSWER:** Denied.

64. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero as to liability for infringement of the '079 patent claims. Hetero's actions have created in Plaintiffs a reasonable apprehension of imminent, irreparable, and substantial harm resulting from Hetero's threatened imminent actions, unless those actions are enjoined by this Court.

**ANSWER:** Hetero admits that there is a real and continuing justiciable controversy between Plaintiffs and Hetero as to liability for infringement of the '079 patent claims. Hetero denies the remaining allegations in Paragraph 64.

65. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '079 patent. Pursuant to 35 § 283, Plaintiffs are entitled to a permanent injunction against further infringement.

**ANSWER:** Denied.

66. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

**REQUEST FOR RELIEF**

Hetero denies that Plaintiffs are entitled to any judgment or relief against Hetero and, therefore, specifically denies Paragraphs A through I of the Complaint's Prayer for Relief. Each averment and/or allegation contained in Plaintiffs' Complaint that is not specifically admitted herein is hereby denied. Hetero requests that judgment be entered in its favor, dismissing Plaintiffs' Complaint without prejudice, awarding Hetero attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

**AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in this Answer, without admitting any averments of Plaintiffs' Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Hetero avers and asserts the following Affirmative Defenses to the Complaint. Hetero expressly reserves the right to allege additional defenses as they become known through the course of discovery.

**FIRST DEFENSE**
**Non-Infringement of the '079 Patent**

Hetero does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '079 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Hetero's ANDA Product does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '079 patent, either

directly, indirectly, contributorily, by inducement, or in any other manner.

**SECOND DEFENSE**
**Invalidity of the '079 Patent**

Each claim of the '079 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

**RESERVATION OF DEFENSES**

Hetero reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

**DEFENDANT HETERO'S COUNTERCLAIMS**

Defendants and Counterclaim-Plaintiffs Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively "Hetero") assert the following counterclaims against Plaintiffs Duchesnay Inc., Shionogi Inc., and QuatRx Pharmaceuticals Company (collectively, "Plaintiffs/Counterclaim-Defendants").

**NATURE OF THE ACTION**

1. Hetero seeks declaratory judgment that one or more claims of U.S. Patent No. 8,642,079 ("the '079 patent") is invalid and/or not infringed.

2. The case arises under the Hatch-Waxman Act, which governs the U.S. Food & Drug Administration's ("FDA") approval of both new and generic drugs. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e).

3. Hetero submitted ANDA No. 215574 ("Hetero's ANDA Product") to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, or importation of a generic product ospemifene, described therein. Plaintiffs/Counterclaim-Defendants' OSPHENA®

is the Reference Listed Drug ("RLD") relied upon in Hetero's ANDA No. 215574.

4. Upon information and belief, Plaintiffs/Counterclaim-Defendants caused the '079 patent to be listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") as allegedly covering OSPHENA® tablets.

5. Under the Hatch-Waxman Act, Hetero was required to submit patent certifications addressing any Orange Book-listed patents.

6. Hetero's ANDA No. 215574 contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications") that the '079 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Hetero's ANDA Product.

7. On February 26, 2021, in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Hetero sent notice to Duchesnay Inc. and QuatRx Pharmaceuticals Company of Hetero's Paragraph IV certifications ("Notice Letter"). Hetero's Notice Letter asserted that the claims of the '079 patent are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA No. 215574, or the products or activities described therein.

8. Hetero's Notice Letter states that "Hetero expressly reserves all rights to raise any additional defenses relating to invalidity, unenforceability, and non-infringement, based *inter alia*, on the facts and information revealed through discovery. Additionally, Hetero expressly reserves the right, if sued, to seek a finding of patent unenforceability due to patent misuse."

9. Hetero's Notice Letter included detailed statements of the legal and factual bases for the Paragraph IV certifications included in ANDA No. 215574 pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c)(7).

10. Upon information and belief, Plaintiffs/Counterclaim-Defendants received Hetero's Notice Letter shortly after it was sent.

11. On April 14, 2021, Plaintiffs/Counterclaim-Defendants filed a Complaint (D.I. 1) against Hetero in the above-captioned action, alleging infringement of the '079 patent.

12. Hetero's declaratory judgment action is necessary to remove the '079 patent as a barrier to Hetero's market entry. The current listing in the Orange Book of the '079 patent delays final approval of Hetero's ANDA No. 215574. But for this patent being listed in the Orange Book, the FDA could grant final approval of Hetero's ANDA No. 215574.

13. Hetero therefore seeks a declaration that the '079 patent is invalid and/or not infringed by Hetero's ANDA Product.

**THE PARTIES**

14. Counterclaimant Hetero Labs Limited is a corporation organized and existing under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500018, Telangana, India.

15. Counterclaimant Hetero Labs Limited Unit-V is a division of Hetero Labs, with its principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

16. Counterclaimant Hetero Drugs Limited is a corporation organized under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500018, Telangana, India.

17. Counterclaimant Hetero USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

18. On information and belief, and as alleged in the Complaint, Counterclaim-

Defendant Duchesnay is a Canadian corporation with its headquarters at 950 Boulevard Michele-Bohec, Blainville, Quebec, Canada J7C 5E2.

19. On information and belief, and as alleged in the Complaint, Counterclaim-Defendant Shionogi is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

20. On information and belief, and as alleged in the Complaint, Counterclaim-Defendant QuatRx is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

## JURISDICTION AND VENUE

21. These counterclaims arise at least under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

22. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j)(5)(C).

23. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs/Counterclaim-Defendants consented to jurisdiction by suing Hetero in this District.

24. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Plaintiffs/Counterclaim-Defendants' choice of forum.

## LEGAL FRAMEWORK AND BACKGROUND

25. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e). The Hatch-Waxman Act was intended to encourage generic-drug

competition while leaving intact incentives for research and development of new drugs by pioneering, *i.e.*, "branded," drug companies. *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648.

26. To accomplish this goal, the Hatch-Waxman Act established a framework with four elements that are pertinent here.

27. First, a company seeking FDA approval of a new drug must submit a New Drug Application ("NDA") to the FDA. *See* 21 U.S.C. § 355. A brand-name drug sponsor must also inform the FDA of every patent that claims the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See* 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(b), 314.53(c)(2). Upon approval of the NDA, the FDA publishes a listing of patent information for the approved drug in the Orange Book. *See* 21 U.S.C. § 355(b)(1). The new FDA-approved drug is known as the "reference-listed drug" or "RLD."

28. Second, the Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an ANDA to the FDA. An ANDA is "abbreviated" because it is generally not required to include the extensive preclinical and clinical data that must be included in an NDA for a brand-name drug. Instead, the ANDA can rely on the NDA's preclinical and clinical data if the proposed generic product is "bioequivalent" to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

29. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market

its generic product; or (iv) that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a "Paragraph IV certification."

30. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and the NDA holder of its Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

31. Third, the Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if the ANDA applicant makes a Paragraph IV certification. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45 days of receiving notice of the Paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval by the FDA of the ANDA to allow the parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

32. Fourth, to encourage prompt generic-market entry, the Hatch-Waxman Act grants the first generic applicant to file a substantially complete ANDA containing a Paragraph IV certification on an Orange Book-listed patent a 180-day period of marketing exclusivity that begins on the earlier of (1) the date it begins commercial marketing of its generic-drug product, or (2) the date of a court decision finding the listed patent(s) invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107(c)(1).

## THE PATENT-IN-SUIT

33. Upon information and belief, Counterclaim-Defendant Duchesnay holds approved NDA No. 203505 for 60 mg tablets containing ospemifene under the name OSPHENA.

34. On its face, the '079 patent is titled "Solid Formulations of Ospemifene" issued

on February 4, 2014.

35. Under 21 U.S.C. § 355(b)(1), an NDA holder must provide to the FDA the patent number and expiration date of any patent(s) that it believes "claims the drug for which the applicant submitted the application or which claims a method of using such drug." The FDA publishes these patents in the Orange Book.

36. Upon information and belief, the '079 patent remains listed in the Orange Book for NDA No. 203505 for OSPHENA ospemifene 60 mg tablets.

**FIRST COUNTERCLAIM**
**Declaratory Judgment of Non-infringement of the '079 Patent**

37. Counterclaimant Hetero incorporates by reference, as though fully set forth herein, Paragraphs 1 through 36 of the Counterclaims.

38. Plaintiffs/Counterclaim-Defendants have alleged in this action that Hetero has infringed the '079 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 215574 ("Hetero's ANDA Product") and that the manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Hetero's ANDA Product would directly infringe, induce others' direct infringement of, and contribute to infringement of the '079 patent in violation of 35 U.S.C. § 271(a), (b), and/or (c).

39. Hetero denies that the filing of Hetero's ANDA Product was an act of infringement and denies that Hetero's manufacture, use, offer for sale, sale, or importation of Hetero's ANDA Product would constitute direct, induced, or contributory infringement of any valid and enforceable claim of the '079 patent.

40. Plaintiffs/Counterclaim-Defendants' suit has restrained the free exploitation of Hetero's non-infringing goods by excluding Hetero from entering the market for the proposed generic tablets described in ANDA No. 215574.

41. There is an actual, immediate, and justiciable controversy between the parties regarding whether the filing of Hetero's ANDA No. 215574 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, and/or will infringe any valid and enforceable claim of the '079 patent.

42. Hetero is entitled to a declaration by this Court that Hetero has not infringed, does not infringe, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid and enforceable claim of the '079 patent, either directly, contributorily, or by inducement and is not liable for any such alleged infringement.

43. Hetero is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

**SECOND COUNTERCLAIM**
**Declaratory Judgment of Invalidity of the '079 Patent**

44. Counterclaimant Hetero incorporates by reference, as though fully set forth herein, Paragraphs 1 through 43 the Counterclaims.

45. The '079 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation. By way of example only, and not by way of limitation, Hetero hereby incorporates by reference the detailed factual and legal basis for its Paragraph IV certification to the '079 patent, served on Duchesnay Inc. and QuatRx Pharmaceuticals Company on or shortly after February 26, 2021, as if set forth fully herein.

46. There is an actual, immediate, and justiciable controversy between the parties.

47. Hetero is entitled to a declaration by this Court that one or more of the claims of the '079 patent is invalid.

48. Hetero is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

**PRAYER FOR RELIEF**

WHEREFORE, Hetero requests that the Court enter judgment in its favor against Plaintiffs/Counterclaim-Defendants as follows:

(a) Adjudicating and/or declaring that Hetero's ANDA No. 215574 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '079 patent;

(b) Adjudicating and/or declaring that the claims of the '079 patent are invalid and/or unenforceable;

(c) Awarding Hetero its reasonable attorneys' fees and costs incurred in this action under 35 U.S.C. § 285;

(d) Granting Hetero such other and further relief as this Court deems just and appropriate; and

(e) Entering judgment in favor of Hetero.

Date: June 14, 2021

Young Conaway Stargatt
& Taylor, LLP

*/s/ Adam W. Poff*
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**CERTIFICATE OF SERVICE**

I, Adam W. Poff, hereby certify that on June 14, 2021, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on June 14, 2021**,** I caused the foregoing document to be served via electronic mail upon the above-listed counsel, and on the following counsel:

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